



DEPARTMENT OF HEALTH AND HUMAN SERVICES

95094d
Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087

September 23, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas J. Clark, CEO
Evercrete International
dba T.J. Clark & Company, Inc.
1145 North 1100 West
Saint George, Utah 84770-8406

Ref #: DEN-04-14

Dear Mr. Clark:

The Food and Drug Administration (FDA) has reviewed your web site at the following internet addresses: <http://www.tjclarkminerals.com>, <http://www.tjclarkinc.com>, <http://www.tjclarkco.com>, <http://www.tjclark.com>, <http://www.tjclarkdirect.com>, <http://www.t-j-clark.com>. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your products T.J. Clark's Catalyzed Melatonin, T.J. Clark Liquid Co-Q10 Advanced Formula, T.J. Clark's Catalyzed Vitamin E, T.J. Clark's Catalyzed Vitamin C, T.J. Clark's Liquid MSM Advanced Formula, T.J. Clark's Catalyzed Chromium Picolinate, T.J. Clark's Life Source Immune Support Package, T.J. Clark's Life Source Mineral Package, T.J. Clark's Life Source Heart Health & Longevity Package, T.J. Clark's Life Source Skin Care Package, T.J. Clark's Life Source Health Complete Package, T.J. Clark's Life Source Weight Loss System Package, T.J. Clark's Life Source Bone and Joint Package, T.J. Clark's Life Source Female Package, T.J. Clark's Life Source Male Package, T.J. Clark's Life Source Children's Package, T.J. Clark's Life Source Sports Nutrition Package, T.J. Clark's Life Source Emotional Support Package, T.J. Clark's Life Source Staying Young After 40 Package, and T.J. Clark's Life Source Energy Max Package. You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g) (1) (B) of the Act]. Your web

sites claim that your products are useful in the prevention, treatment, and mitigation of diseases.

Products and objectionable claims include the following:

T.J. Clark's Catalyzed Melatonin:

"Melatonin...appears to be the body's natural defense against breast cancer."
"[M]elatonin can be beneficial in treating children who have sleep disorders associated with autism, epilepsy, Down's syndrome and cerebral palsy."
"Another important ingredient of our melatonin is L-Glutamine. L-Glutamine supplements can be helpful in the treatment of arthritis, autoimmune diseases, fibrosis, intestinal disorders, peptic ulcers, connective tissue diseases, and tissue damage due to radiation treatment for cancer...It has been used to treat problems such as epilepsy,...impotence, schizophrenia...."

T.J. Clark Liquid Co-Q10 Advanced Formula:

"[A] very beneficial supplement for individuals who suffer from disorders of the cardiovascular system...."
"Revive failing hearts...Lower blood pressure"

T.J. Clark's Catalyzed Vitamin E:

"[F]ights cancer and cardiovascular disease"
"[R]educes DNA damage in cells that can lead to mutations and cancer"
"[C]an improve...chronic fatigue syndrome"
"[M]ay ease angina and arthritis pain"
"[B]oosts HDL levels (the lipoprotein that carries cholesterol away from the cell)"

T.J. Clark's Catalyzed Vitamin C:

"[H]elps prevent cancer and protects against infection."
"[M]ay reduce cholesterol levels and high blood pressure because it protects against blood clotting, and bruising,"
"[P]romotes the healing of wounds and burns..."

T.J. Clark's Liquid MSM Advanced Formula:

"MSM may help relieve...Arthritis (Osteo-arthritis)...Rheumatoid Arthritis...Fibromyalgia...Tendonitis...Carpal Tunnel Syndrome...TMJ (Temporomandibular Joint Syndrome)...Asthma."
"MSM provides major pain relief...."

T.J. Clark's Catalyzed Chromium Picolinate:

"Taking chromium supplements may help ... lower triglycerides ...raise good-type HDL cholesterol ...discourage artery-clogging and heart disease...lower bad-type blood cholesterol ...normalize blood sugar... reduce the risk of adult-onset diabetes ...thwart cancer growth."

T.J. Clark's Life Source Immune Support Package

"Liquid Grape Seed Extract Advance Formula.... Its most common applications are used in the following conditions: ... Cardio-protection (reduce the risk of arteriosclerosis) ...Diabetes conditions (neuropathy... retinopathy) ...Reduce Cancer risk ...ADD/ADHD ...It may also have benefits for the healing of wounds and injuries..."

"Liquid Co-Q 10 Advanced Formula....[V]ery beneficial supplement for individuals who suffer from disorders of the cardiovascular system."

T.J. Clark's Life Source Mineral Package

"[T]aken as directed, our specially formulated mineral supplements may help to reduce the risk of Osteoporosis, stabilize blood pressure levels, ...regulate blood sugar levels, prevent infection and heal wounds..."

T.J. Clark's Life Source Heart Health & Longevity Package

"Our Liquid Coenzyme Q10 formula.... [S]tudies show [Coenzyme Q10] can benefit those individuals suffering from cardiovascular disorders, ...and auto-immune disorders."

"Liquid Grape Seed Extract formula.... Used for a verity [sic] of conditions including ...cardio-protection (reduce the risk of arteriosclerosis)..."

"Liquid Catalyzed Chromium Picolinate....According to recent studies chromium supplements may help in the fight to lower bad-type LDL cholesterol and lower triglycerides with helping to raise good-type HDL levels thus discouraging artery-clogging and heart disease."

"Catalyzed Vitamin E capsules.... [H]elps fight...atherosclerosis, the gradual clogging and hardening of the arteries.... [H]as been shown effective in blocking oxidation of detrimental LDL cholesterol...reducing plaque build up in the arteries."

T.J. Clark's Life Source Skin Care Package [not on tjclarkdirect.com]

"Taking chromium supplements may help: lower triglycerides ... raise good-type HDL cholesterol ... discourage artery clogging and heart disease ... lower bad-type blood cholesterol ... normalize blood sugar ... reduce the risk of adult-onset diabetes ... thwart cancer growth"

"According to studies, some of the reasons why Co-Q10 supplements are necessary are that it may:... Save arteries ... Revive failing hearts ... Lower blood pressure (improvements in heart function)"

"T.J. Clark Catalyzed Vitamin C...Some of the other functions of vitamin C are: helps prevent cancer and protects against infection ...may reduce cholesterol levels and high blood pressure because it protects against blood clotting... promotes the healing of wounds and burns...."

These claims cause your products to be drugs, as defined in section 201(g) (1) (B) of the Act. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

Furthermore, we found that your web sites at www.tjclarkinc.com, www.tjclarkminerals.com, www.tjclarkdirect.com, and www.tjclarkco.com list numerous diseases (e.g., herpes, HIV/AIDS, HPV/cervical cancer) with a link for each disease. By clicking the link for a particular disease, the viewer is directed to a page about the disease. Each of these pages contains links (e.g., "Click Here for the SOLUTION") that lead the viewer to a list of your Life Source product "packages" available for sale on the website. This also causes the Life Source product packages to be drugs because the website implies that these products are the "solution" (i.e., a treatment or cure) for the listed diseases.

This letter is not intended to be an all-inclusive review of products sold on your Internet web sites or your firm's other products and their labeling. You are responsible for ensuring that all products marketed by your firm are in compliance with applicable United States laws.

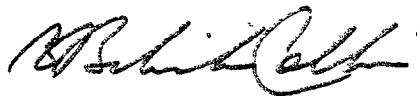
We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by FDA without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

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Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to the attention of Ms. Shelly Maifarth, Compliance Officer, Food and Drug Administration at the attached letterhead address.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Belinda Collins", with a stylized flourish at the end.

B. Belinda Collins
District Director